510(k) Summary

JUL 25 2012

Centrix, Inc.

Senzzzzz Away

July 12, 2012

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Centrix, Inc. 770 River Road Shelton, CT 06484 Telephone: +1 (203) 929-5582 Fax: +1 (203) 929-6804
Official Contact:	Greg Moreau RA/QA Director
Representative/Consultant:	Linda K. Schulz Allison C. Komiyama Floyd G. Larson PaxMed International, LLC 11234 El Camino Real, Suite 200 San Diego, CA 92130 Telephone: +1 (858) 792-1235 Fax: +1 (858) 792-1236 Email: lschulz@paxmed.com akomiyama@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	Senzzzzz Away
Classification Name:	Cavity Varnish
Classification Regulations:	21 CFR 872.3260, Class II
Product Code:	LBH
Classification Panel:	Dental Products Panel
Reviewing Branch:	Dental Devices Branch

INTENDED USE

Senzzzzz Away™ is to be used to relieve dental hypersensitivity.
or
D/Sense® Crystal™ is to be used to relieve dental hypersensitivity.

DEVICE DESCRIPTION

Senzzzzz Away is an oxalate tooth desensitizing agent intended for over-the-counter-use.
The combination of tubule occlusion and reduction in nerve excitability shown with oxalate formulations is responsible for the reduction in dentinal hypersensitivity to cold, hot and sweets.
Senzzzzz Away is a one-part, opaque gel for single use.

EQUIVALENCE TO MARKETED DEVICE

Centrix, Inc., D/Sense® 1-Step cleared under K021146,

Phoenix Dental, Inc., Super Seal® Tooth Desensitizer cleared under K983477 and K120109

Sunstar Butler, Protect™ Tooth Desensitizer cleared under K050486

NovaMin Technology, Inc., Oralief™ Therapy for Sensitive Teeth cleared under K040858

Remedent NV, Remesense cleared under K082594

Bisco, Inc., BisBlock cleared under K033521

Ultradent Products, Inc., UltraEZ Desensitizing Gel cleared under K061438

Comparison of Technological Characteristics

Device Name	Classification Name	Mode of Action	Application	Material
Senzzzzz Away (or D/Sense Crystal)	Cavity varnish, Calcium hydroxide cavity liner	Tubule Occlusion	Paint-on gel	Oxalate
D/Sense® 1-Step	Calcium hydroxide cavity liner	Tubule Occlusion	Paint-on gel	Oxalate
Super Seal® Tooth Desensitizer	Cavity varnish	Tubule Occlusion	Applicator	Oxalate
Protect™ Tooth Desensitizer	Cavity varnish	Tubule Occlusion	Paint on liquid	Oxalate
Oralief™ Therapy for Sensitive Teeth	Cavity varnish	Tubule Occlusion	Brush on paste	Calcium sodium phosphosilicate
Remesense	Cavity varnish	Tubule Occlusion	Tray and foam strips	Oxalate
BisBlock	Calcium hydroxide cavity liner	Tubule Occlusion	Etch+apply liquid+seal	Oxalate
UltraEZ Desensitizing Gel	Cavity varnish	Tubule Occlusion	Tray and gel	Potassium nitrate Fluoride ion gel

Senzzzzz Away tooth desensitizer is the over-the-counter version of D/Sense® Crystal™ (previously D/Sense® 1-Step). Senzzzzz Away is packaged in a single use tray with applicator for consumer use. All of the predicates use tubule occlusion as a mechanism for controlling dental hypersensitivity. Oxalate formulations also have an effect on nerve excitability to reduce pain sensitivity.

Side-by-side biocompatibility testing was performed on the subject and predicate devices. Scanning electron microscopy images of extracted teeth before and after device application demonstrated that the device seals and occludes dentinal tubules.

A consumer ease-of-use study conducted for Senzzzzz Away to ensure that patient use of the product was appropriate for over-the-counter purchase. A six month effectiveness study was performed to demonstrate the reduction in sensitivity. The combination of these studies shows Senzzzzz Away is safe and effective for over-the-counter use.

Overall, Senzzzzz Away has the following similarities to the predicate devices:

- has the same intended use,
- uses a similar operating principle,
- incorporates the same basic design,
- incorporates the same or similar materials, and
- has similar packaging.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG – 3 2012

Centrix, Incorporated
C/O Ms. Linda K. Schulz
PaxMed International, LLC
11234 Camino Real, Suite 200
San Diego, California 92130

Re: K120176
Trade/Device Name: Senzzzzz Away™ (OTC), D/Sense® Crystal™ (Rx)
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: II
Product Code: LBH
Dated: June 29, 2012
Received: July 2, 2012

Dear Ms. Schulz:

This letter corrects our substantially equivalent letter of July 25, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

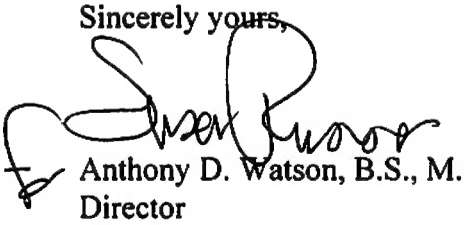
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K120176

Device Name: Senzzzzz Away™ (OTC), D/Sense® Crystal™ (Rx)

Indications for Use:

To relieve dental hypersensitivity.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120176